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TRABECTOME (TRABECULECTOMY—INTERNAL APPROACH): ADDITIONAL EXPERIENCE AND EXTENDED FOLLOW-UP

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ABSTRACT

Purpose: To report a retrospective case series of 1127 Trabectome surgical procedures, including 738 Trabectome-only and 366 Trabectome-phacoemulsification surgeries.

Methods: Electroablation of meshwork via a temporal corneal incision. Outcomes included changes in intraocular pressure (IOP) and medication use, complications, and Kaplan-Meier success estimates.

Results: For all cases, mean preoperative IOP of 23.8 ± 7.7 mm Hg decreased by 39% to 16.5 ± 4.0 mm Hg at 24 months (n = 50). Intraoperative reflux bleeding occurred in 77.6%. Medications decreased from 2.8 to 1.2 by 24 months. Sixty-five patients (5.8%) had IOP elevation > 10 mm Hg above baseline on day 1. Failure led to trabeculectomy in 5.9% (n = 67) and shunt installation in 1.6% (n = 18). Kaplan-Meier failure was defined across groups with at least 2 weeks follow-up as IOP > 21 mm Hg with or without medications and not reduced by 20% below baseline on 2 consecutive visits or repeat surgery.

For Trabectome-only cases, mean preoperative IOP of 25.7 ± 7.7 mm Hg was reduced by 40% to 16.6 ± 4.0 mm Hg at 24 months (n = 46). No prolonged hypotony, choroidal effusion, choroidal hemorrhage, or infections occurred. Failure led to trabeculectomy in 8.1% (n = 60) and shunt installation in 1.9% (n = 14). Medications decreased from 2.93 to 1.2 by 24 months.

For Trabectome-phacoemulsification cases, baseline IOP of 20.0 ± 6.2 mm Hg decreased at 12 months to 15.9 ± 3.3 mm Hg (18%) (n = 45) and medications decreased from 2.63 ± 1.12 to 1.50 ± 1.36. Sixteen (4.4%) of 365 had prior failed trabeculectomy, and 139 of 365 (38%) had prior laser trabeculoplasty.

Conclusion: Trabectome offers a minimally invasive method of improving IOP control in open-angle glaucomas.

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INTRODUCTION

The Trabectome, cleared by the US Food and Drug Administration in April 2004, was first used in the United States in January 2006 for surgical treatment of open-angle glaucoma. Now in its third year of widening commercialization and clinical utilization in all age-groups, it has been employed in 46 glaucoma centers in the United States, Canada, Mexico, and Japan. Three peer-reviewed publications have described and illustrated the instrument, intraocular pressure (IOP) outcomes in the initial 37 cases performed in Mexico, and a subsequent case series expanded to 89 patients with 30 months follow-up for 10 eyes from among the original 37 cases.[1-3] The unique aspect of this procedure includes the electrosurgical ablation of trabecular meshwork and debris aspiration to improve aqueous access to collector channels, most numerous nasally.[4,5] Also, the device's footplate protects adjacent tissues during ablation. This report includes demographics on the overall group and separate descriptive statistics and survival analyses for Trabectome-only and combined Trabectome-phacoemulsification cases.

METHODS

Data for this report have been collected with local Institutional Review Board approval, in accordance with the Declaration of Helsinki and the Health Insurance Portability and Accountability Act. Procedure modifications that have been recommended since the previously published method descriptions include topical application of apraclonidine 0.5% or brimonidine 0.1% per surgeon preference to reduce intraoperative reflux bleeding. Among early cases, anesthesia was usually induced via retrobulbar needle or sub-Tenon irrigation. Now intracameral preservative-free lidocaine 1% to 2% is often used. Hydroxymethylcellulose (OcuCoat, Bausch & Lomb, Rochester, NY) has remained the recommended viscoelastic, if needed, to deepen and stabilize the anterior chamber. A Simcoe cannula is now included with the surgical pack for use as needed to remove residual blood after Trabectome-only surgery. With experience, most surgeons experienced in Trabectome use now report treating 60^{o} to 120^{o} of angle. Technique variations since the original reports have included use of higher power levels during tissue ablation, now averaging 700 to 800 mW, as well as deferring the use of viscoelastic in the anterior chamber of pseudophakic eyes, as it is usually not necessary.

Topical medications used before surgery are resumed or titrated downward postoperatively, according to surgeon preference, depending on the desired IOP goal range.

PATIENTS

Typical candidates for Trabectome surgery are phakic or pseudophakic eyes of adults or children with uncontrolled open-angle glaucoma and a clear gonioscopic view. Demographic data for all cases, including combined procedures, are summarized in Table 1. The age range of patients was 3 days to 96 years, with a mean age of 69 ± 15 years. Many eyes at relatively high risk for filtering

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Bold type indicates AOS member.

surgery failure were included after prior failed trabeculectomy or other previous surgeries.

Eyes with extensive peripheral anterior synechiae covering the meshwork were excluded, but a few eyes with limited peripheral anterior synechiae were included and three combined Trabectome-phacoemulsification procedures included goniosynechialysis (Table 1).

TABLE 1. CHARACTERISTICS OF PATIENTS WITH UNCONTROLLED OPEN-ANGLE GLAUCOMA TREATED WITH TRABECTOME

VARIABLE	VALUE
Total number	1127
Age	
Mean	69 yr
SD	15 yr
Minimum	3 days
Maximum	96 yr
(Age 3 days to 18 years)	18
Sex	
Male	447
Female	625
Race (self-defined)	
African American	77
Asian	39
Caucasian	751
Hispanic	977
Other	163
Laterality	
OD	594
OS	515
(Not stated)	18
Glaucoma type	
POAG	818
Exfoliation	109
Juvenile rheumatoid arthritis	5
Steroid-induced	20
Pigment dispersion	37
Uveitis-related	29
Other (not indicated)	109
Other ocular diagnosis	
Myopic degeneration	5
CRVO	1
Preop Snellen acuity	
20/20 – 20/40	538
20/50 – 20/70	203
20/80 – 20/100	68
20/200 – 20/400	91
<20/400	54
Not reported	173
Visual field status (damage)	
Minimal (1 quadrant)	57
Moderate (2 quadrants)	270
Advanced (>2 quadrants)	372
Not reported	428
Lens status	
Pseudophakic	326
Phakic	727
Aphakic	5

TABLE 1 (CONTINTUED) CHARACTERISTICS OF PATIENTS WITH UNCONTROLLED OPEN-ANGLE GLAUCOMA TREATED WITH TRABECTOME

VARIABLE	VALUE
Angle: Shaffer grade	
I	15
II	86
III	354
IV	434
Not reported	238
Cup-disc ratio	
<0.7	221
0.7 – 0.8	337
>0.8	425
Not reported	144
Prior surgery	
SLT	273
ALT	170
Aqueous shunt	20
Trabeculectomy	104
Prior Trabectome	5
Vitrectomy	4
Laser iridectomy	5
Endocyclophotocoagulation	3
YAG capsulotomy	2
Retinal surgery	15
Combined surgeries	
Trabectome-phaco	366
Trabectome- goniosynechialysis	3
Aqueous shunt at same operation	7
Trabectome and PK	1
Trabectome and ECP	1
Trabectome and bleb revision	2

ALT, argon laser trabeculoplasty; CRVO, central retinal vein occlusion; ECP, endolaser cyclophotocoagulation; PK, penetrating keratoplasty; POAG, primary open-angle glaucoma; SLT, selective laser trabeculoplasty.

STATISTICAL METHODS

Summaries of changes in IOP and medication use (Tables 1 through 3; Figures 1 through 8) include Kaplan-Meier survival graphs for all cases (Figure 3), Trabectome-only cases (Figure 4), and Trabectome-phacoemulsification cases (Figure 5). Survival graphs were calculated using SAS 9.1 (SAS Institute, Cary, North Carolina). *Failure* (definition 1) was IOP greater than 21 mm Hg and not reduced by 20% below baseline on 2 consecutive visits after 2 weeks follow-up or subsequent surgery, similar to the definitions utilized in the recent Tube Versus Trabeculectomy (TVT) study.[6,7] We also included a survival analysis (definition 2) with *failure* defined as IOP greater than 21 mm Hg or not reduced by 20% below baseline on 2 consecutive visits after 2 weeks follow-up or subsequent surgery (Figure 8). Mean change in IOP from baseline and decrease in medication use are shown in Table 2 for Trabectome-only and in Table 3 for combined Trabectome-phacoemulsification cases by follow-up month.

RESULTS

The decrease in IOP among Trabectome-only cases with or without medications was 40% at 24 months (n = 46) (Table 2), 41% at 36 months (n = 35), and 32% at 60 months (n = 2) to 16.4 ± 4.5 mm Hg, down from a mean preoperative IOP of 25.7 ± 7.7 mm Hg (Table 2, Figure 1). The mean decrease in adjunctive medication use for Trabectome-only cases was 39%, from a preoperative mean of 2.9 ± 1.30 to a postoperative mean of 1.8 ± 1.4 antiglaucoma medications (Table 2, Figure 2). Failure, defined as additional glaucoma surgery (Trabectome, trabeculectomy, aqueous shunt, laser trabeculoplasty, cyclophotocoagulation), has been reported in 100 of 738 Trabectome-only cases (14%) (Table 2). Twelve of 100 surgical failures occurred by 2 weeks, 76 of 100 by 6 months, and 95 of 100 by 18 months, demonstrating that clinical failure defined by a subsequent glaucoma surgery is most likely during the first postoperative year (Table 2). Two patients (3 eyes) in the study have died since the original report in 2005.

TABLE 2. CHANGES IN INTRAOCULAR PRESSURE (IOP) AND MEDICATION USE AFTER TRABECTOME-ONLY SURGERY

TIME OF EXAMINATION	IOP (MM HG)		% REDUCTION	N	SECOND SURGERY		MEDICATION USE	
	MEAN	SD			CUMULATIVE NO.	%	NO. OF DRUGS	SD
Preop IOP with/without medication	25.7	7.7		738			2.93	1.29
1 day	16.6	8.8	-31%	699	1	0	2.04	1.71
3 days	16.7	6.9	-31%	649	1	0	2.17	1.70
1 wk	16.9	6.8	-315	656	2	0	2.55	1.57
2 wk	17.7	6.9	-27%	610	12	2	2.56	1.54
1 mo	17.3	6.0	-28%	571	23	3	2.41	1.46
2 mo	16.5	5.3	-31%	494	42	6	2.24	1.42
3 mo	16.5	4.7	-31%	425	53	7	2.16	1.44
4 mo	16.4	4.2	-31%	353	65	9	2.01	1.38
5 mo	16.4	4.0	-32%	296	73	10	1.96	1.38
6 mo	16.5	4.2	-31%	260	76	10	1.84	1.41
7 mo	16.3	3.6	-32%	212	86	12	1.83	1.39
8 mo	16.0	3.7	-34%	181	86	12	1.80	1.45
9 mo	15.8	3.3	-36%	147	90	12	1.66	1.43
10 mo	15.8	3.6	-37%	129	90	12	1.51	141
11 mo	16.0	3.1	-37%	111	90	12	1.41	1.36
12 mo	16.1	3.0	-37%	102	93	13	1.50	1.27
15 mo	16.0	3.1	-38%	87	93	13	1.44	1.19
18 mo	16.1	2.9	-40%	67	95	13	1.22	1.13
21 mo	16.2	3.4	-42%	54	96	13	1.35	1.05
24 mo	16.6	4.0	-40%	46	97	13	1.24	0.92
30 mo	16.6	3.0	-40%	40	98	13	1.23	0.97
36 mo	16.4	2.7	-41%	35	98	13	1.00	0.94
40 mo	16.6	3.0	-40%	32	99	13	1.03	1.03
44 mo	15.9	2.1	-41%	28	100	14	0.82	0.82
48 mo	16.1	1.9	-40%	20	100	14	0.89	0.81
52 mo	16.3	2.2	-37%	13	100	14	1.15	0.80
56 mo	16.1	1.4	-36%	8	100	14	0.88	0.64
60 mo	17.5	0.7	-32%	2	100	14	0.50	0.71
Mean	16.4	4.5	-35%				1.8	
SD			4%					1.4

Mean preoperative IOP among combined Trabectome-phacoemulsification cases (Table 3) with or without medications decreased 21% at 6 months (n = 143), 18% at 12 months (n = 45), and an overall mean of 20%, from 20.0 ± 6.2 mm Hg to 15.5 ± 4.0 mm Hg at 30 months (Table 3). Medication use decreased from a preoperative mean of 2.93 ± 1.29 to 2.0 ± 2.83 at 30 months.

Complications and adverse events among all cases to date have included transient elevation of IOP, defined as IOP exceeding 10 mm above baseline at day 1, reported in 65 of 1127 cases (5.8%) (Table 4). Intraoperative blood reflux has occurred in most eyes (78%) but typically cleared over a few days and has not consistently correlated with IOP elevation. Visual acuity decrease (≥2 Snellen lines) due to progression of cataract after Trabectome surgery was reported in 1 among 101 cases included in the 2006 update[3] that underwent cataract surgery 21 months post-Trabectome. Visual acuity decrease ≥2 Snellen lines has not been reported after subsequent Trabectome surgery. No cases of postoperative endophthalmitis or choroidal hemorrhage have been reported.

TABLE 3. CHANGES IN INTRAOCULAR PRESSURE (IOP) AND MEDICATION USE AFTER COMBINED TRABECTOME-PHACOEMULSIFICATION SURGERY

TIME OF EXAMINATION	IOP (MM HG)		% REDUCTION	N	SECOND SURGERY		MEDICATION USE	
	MEAN	SD			CUMULATIVE NO.	%	NO. OF DRUGS	SD
Preop IOP with/without medication	20.0	6.2		366			2.93	1.29
1 day	17.8	9.0	-7%	355	0	0	1.67	1.57
3 days	16.9	7.2	-11%	335	2	1	1.76	1.58
1 wk	16.0	6.0	-16%	338	4	1	2.10	1.41
2 wk	15.7	5.2	-18%	322	7	2	2.15	1.38
1 mo	15.2	4.6	-20%	314	9	2	2.09	1.34
2 mo	15.1	3.8	-20%	280	10	3	1.81	1.35
3 mo	14.7	3.7	-23%	235	10	3	1.78	1.31
4 mo	14.7	3.5	-22%	191	12	3	1.71	1.36
5 mo	15.0	3.6	-20%	163	13	4	1.63	1.29
6 mo	14.8	3.2	-21%	143	13	4	1.64	1.27
7 mo	14.6	3.2	-21%	113	12	3	1.60	1.31
8 mo	15.0	3.1	-20%	102	12	3	1.65	1.35
9 mo	15.0	3.6	-20%	86	12	3	1.69	1.39
10 mo	14.7	3.1	-22%	70	12	3	1.54	1.39
11 mo	15.3	3.4	-17%	56	12	3	1.52	1.25
12 mo	15.9	3.3	-18%	45	12	3	1.50	1.36
15 mo	15.8	2.6	-17%	33	13	4	1.64	1.48
18 mo	15.8	3.2	-19%	20	13	4	1.40	1.10
21 mo	16.0	3.1	-25%	10	13	4	1.60	1.35
24 mo	14.9	3.1	-30%	4	13	4	1.25	1.89
30 mo	16.5	3.5	-42%	2	13	4	2.00	2.83
Mean	15.5	4.0	-20%				1.7	
SD			7%					1.5

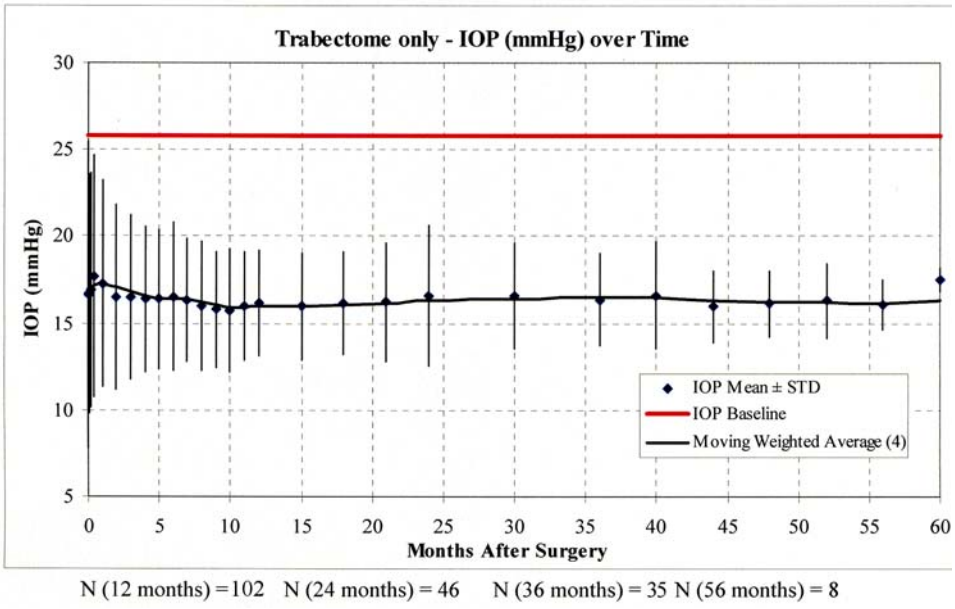

FIGURE 1

Changes in intraocular pressure (IOP) in Trabectome-only cases (N = 738)

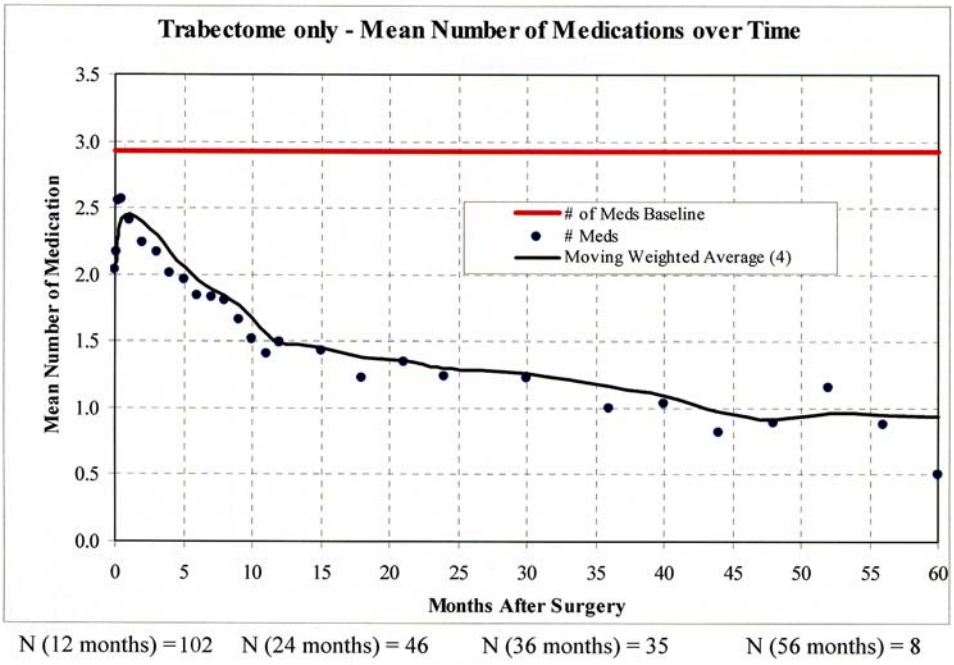

FIGURE 2

Changes in adjunctive medication use in Trabectome-only cases (N = 738).

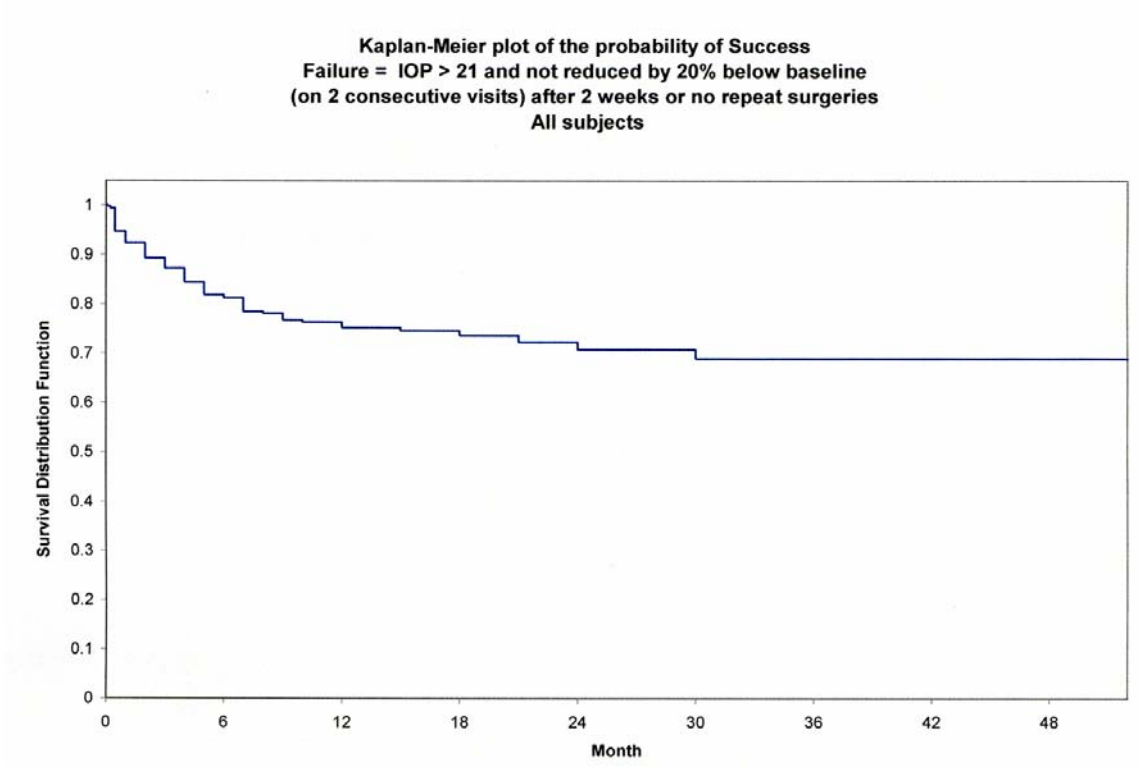

FIGURE 3

Kaplan-Meier plot of probability of success, according to failure definition 1, in all cases (N = 1127).

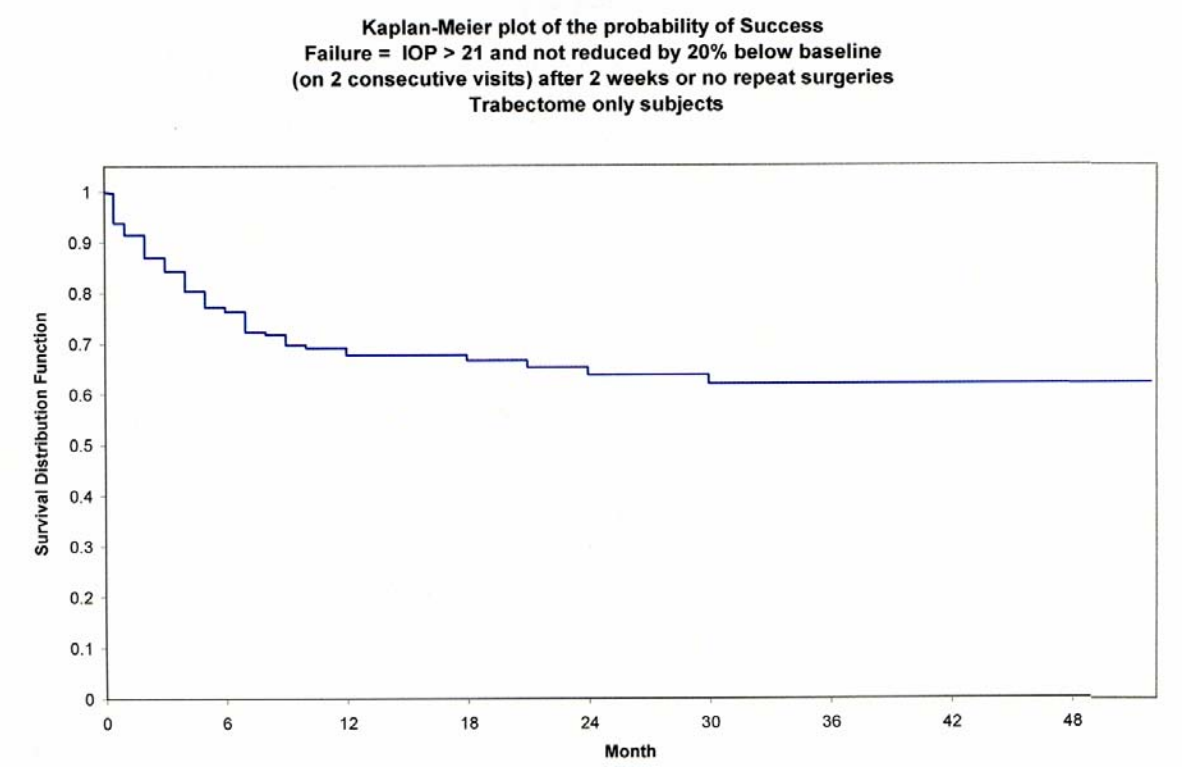

FIGURE 4

Kaplan-Meier plot of probability of success, according to failure definition 1, in Trabectome-only cases (N = 738).

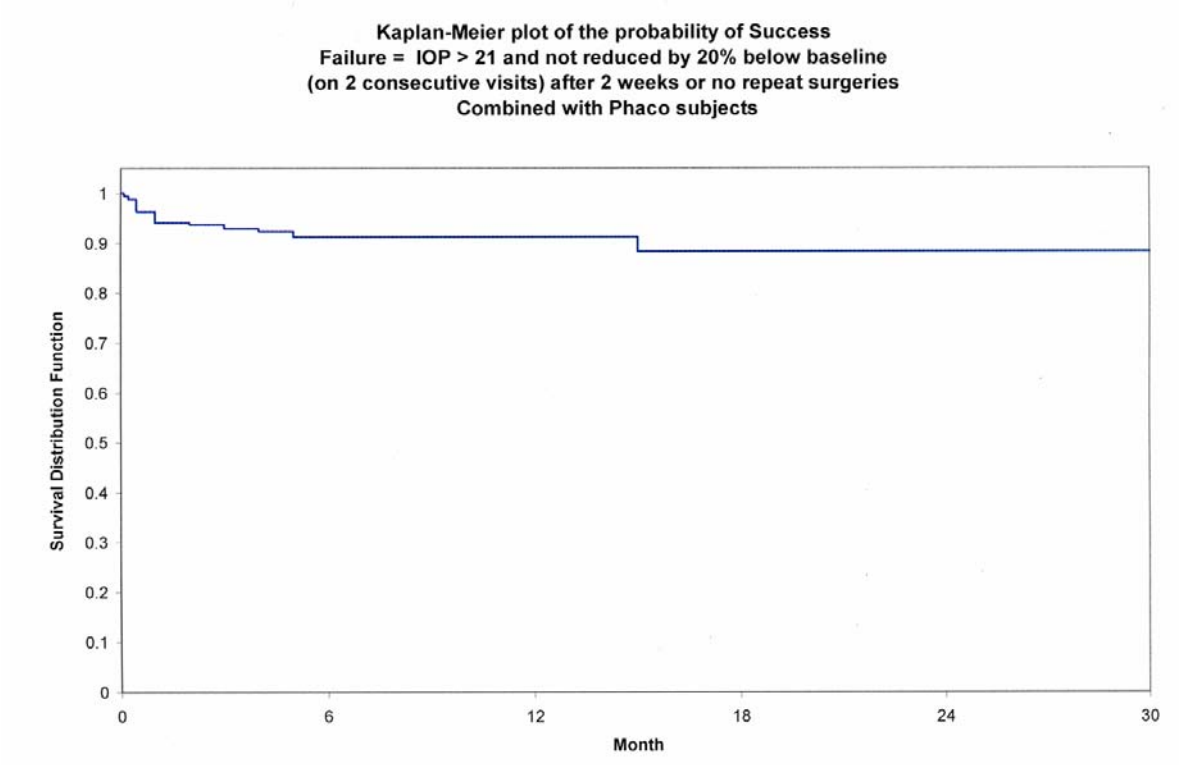

FIGURE 5

Kaplan-Meier plot of probability of success, according to failure definition 1,
in combined Trabectome and phacoemulsification (N = 366).

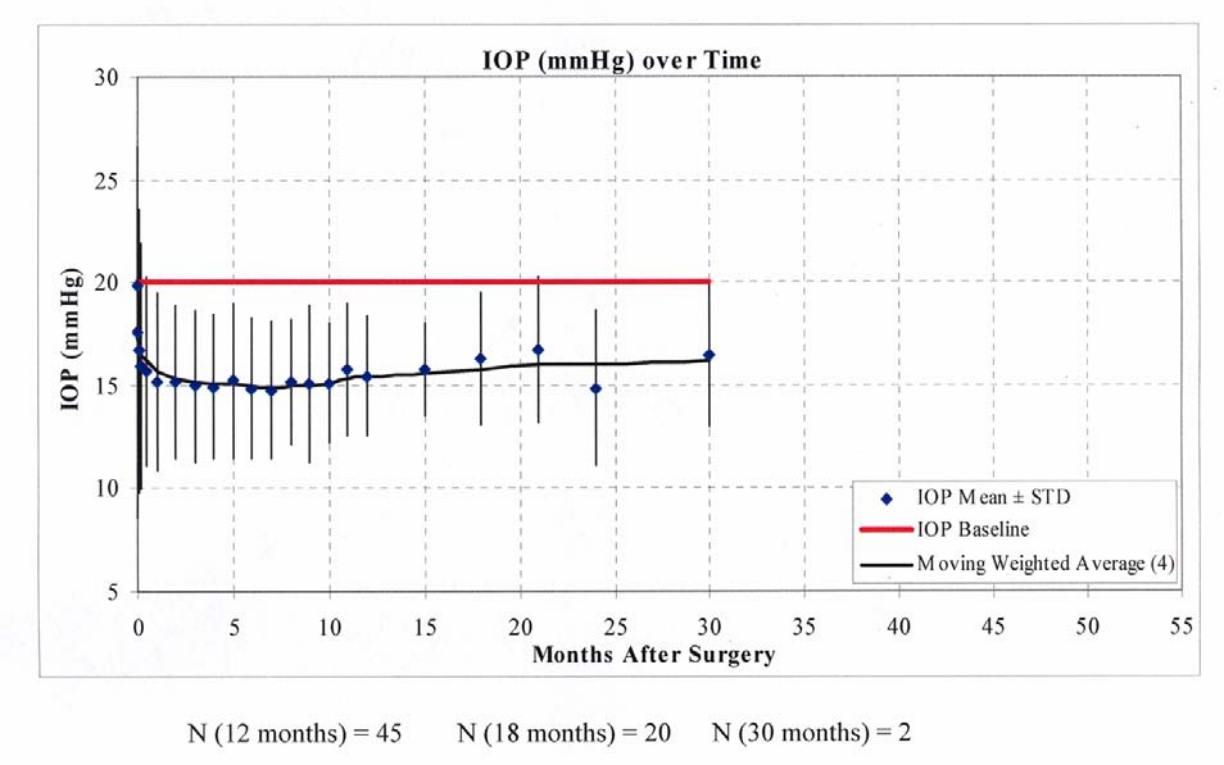

FIGURE 6

Changes in intraocular pressure (IOP) in Trabectome-phacoemulsification cases (N = 366).

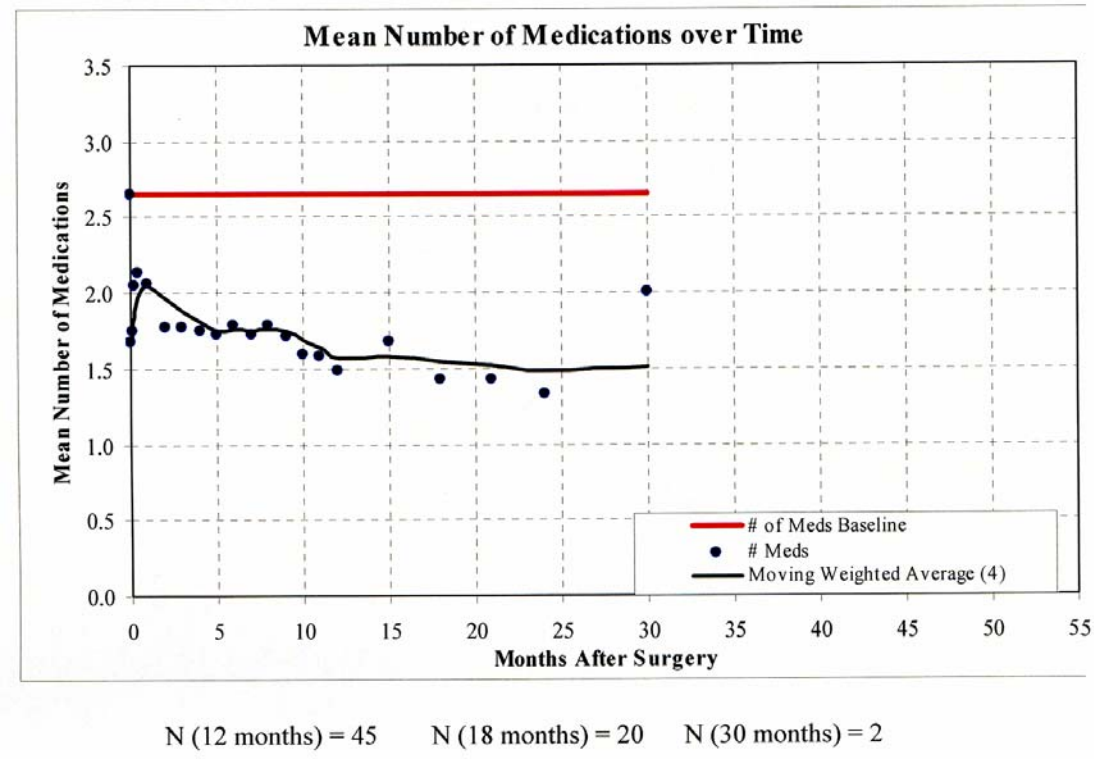

FIGURE 7

Changes in adjunctive medication use in Trabectome-phacoemulsification cases (N = 366).

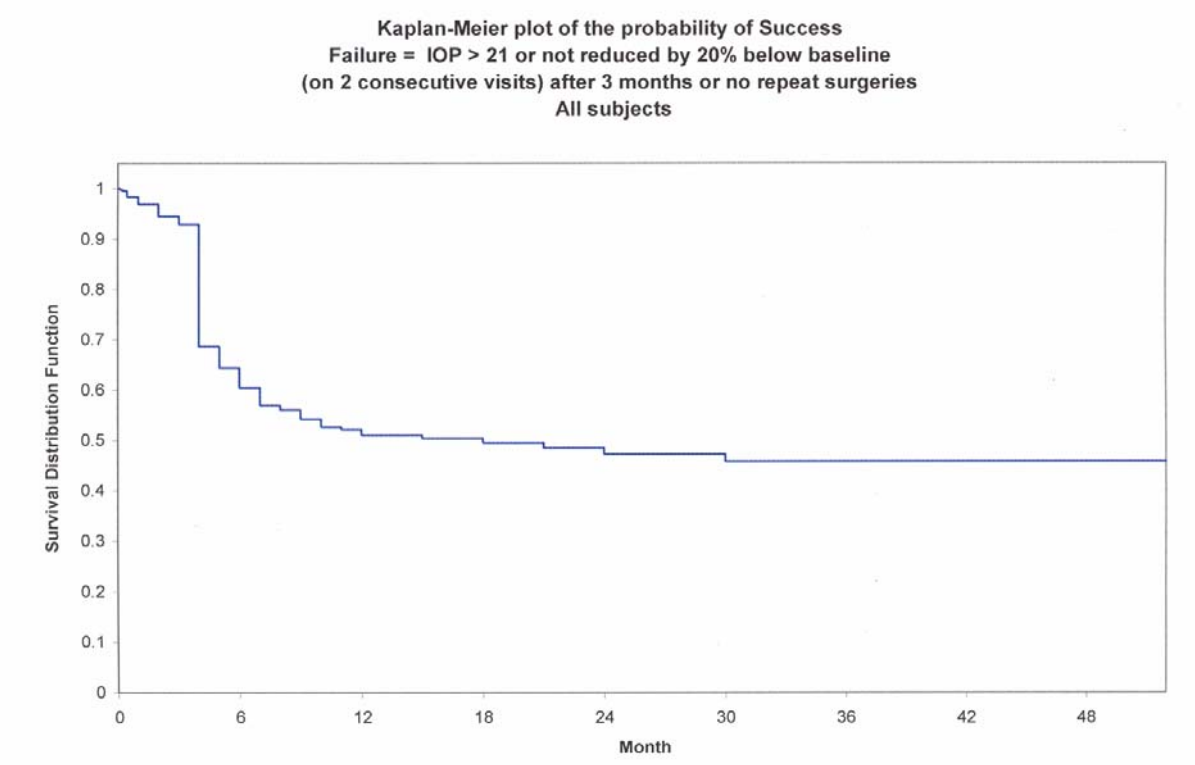

FIGURE 8

Kaplan-Meier plot of probability of success, according to failure definition 2, in all cases (N = 1127).

TABLE 4. COMPLICATIONS AND ADVERSE EVENTS AMONG ALL CASES OF TRABECULOME SURGERY

Total number of patients	1127
Trabeculectomy	67
Aqueous shunt	18
Diode cyclophotocoagulation	3
Selective laser trabeculoplasty	5
Phacoemulsification	1
Endocyclophotocoagulation	1
ExPRESS shunt	1
Repeat Trabectome (patient request)	10
Trabectome with shunt ligature release	5
Other secondary surgeries	7
Total secondary surgeries reported	113
Patient deaths during follow-up (unrelated)	3
Sustained hypotony (IOP <5 mm Hg 1 mo postoperatively)	0
Hypotony (IOP <5 mm Hg day 1)	17
IOP spike (IOP >10 mm Hg above baseline day 1)	65
Aqueous misdirection	1
Infection	0
Wound leaks	0
Bleb formation	0
Problematic pain	0
Choroidal effusion	0
Choroidal hemorrhage	0
Visual acuity decrease >2 lines	0

TABLE 4 (CONTINUED). COMPLICATIONS AND ADVERSE EVENTS AMONG ALL CASES OF TRABECULOME SURGERY	
Intraoperative blood reflux reported (874/1127 [78%])	874
None noted	55
Not reported	198

IOP, intraocular pressure; SLT, selective laser trabeculoplasty.

DISCUSSION

Limitations of this retrospective case series include small numbers at longer-term follow-up intervals in both Trabectome-only and Trabectome-phacoemulsification subsets. Although the instrument supplier requires reporting of results back to the database for the first 20 cases performed by a participating surgeon, reporting on cases beyond the initial 20 and long-term reporting of previous cases are voluntary and no doubt incomplete. This update on 1127 surgeries likely did not include all cases performed by several surgeons, as the total number of handpieces sold by the company is much larger than 1127, even allowing for inventory of extra handpieces at some facilities. As with any retrospective noncomparative case series, patient selection and data collection lack the rigor and consistency usually practiced during a prospective randomized trial. Dwindling numbers of patients with follow-up beyond many months render long-term efficacy difficult to evaluate and may explain the apparent decrease in IOP standard deviation with longer-term follow-up. Loss to follow-up has no doubt occurred but cannot be precisely tabulated, since recruitment and follow-up data collection are ongoing and data submission is voluntary beyond 1 year. Sample size and power calculations were not made, and no control group was included. Survival curves using the TVT study criterion, which compared trabeculectomy to the Baerveldt aqueous shunt, are included, as in many instances these alternative filtering procedures would be considered for patients such as those reported here. The survival curve for the entire group using failure definition 2 ("or" instead of "and") provides a less optimistic outcome but more realistically portrays expected IOP decrease among those cases (especially low-tension glaucomas) starting with IOPs less than 21 mm Hg.

The optimum arc of angle necessary to treat is unknown. Preliminary analysis using goniophotography suggests minimal correlation between the ablation arc and IOP outcomes (Khaja HA, Hodge DO, Sit A, Poster 4191, ARVO annual meeting; April 27-May 1, 2008, Fort Lauderdale, Florida). Possibly the more important issues are that the ablated areas remain open and are in proximity to collector channel openings.

CONCLUSIONS

Trabectome offers a safe and effective alternative to standard filtering surgery that importantly does not preclude subsequent procedures, as the conjunctiva is not manipulated. It may not be appropriate in cases thought to require especially low IOP. Considering that the data presented here are based primarily on the initial procedures done by new users, albeit including many with expertise in gonioscopy, the results are very unlikely to have been biased by high skill levels among surgeons or by selection of favorable cases, as many were at relatively high risk for failure (Table 1). This large case series has established that this procedure has low complication rates and is likely to improve IOP control on fewer medications.

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Author Contributions: Design and conduct of the study (D.M., B.F., S.M.); Collection, management, analysis, and interpretation of data (L.D., D.M.); Preparation, review, and approval of the manuscript (D.M., B.F., S.M., L.D.).

Conformity With Author Information: Data were collected with local Institutional Review Board approval, in accordance with the Declaration of Helsinki and the Health Insurance Portability and Accountability Act.

APPENDIX

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PEER DISCUSSION

DR. ANNE LOUISE COLEMAN: The authors are to be congratulated for reporting the results from post-marketing surveillance of a new surgical procedure for glaucoma, the Trabectome®. The first 20 patients plus additional patients who had the Trabectome® at 46 glaucoma centers since January 2006 were included in this manuscript if their data were available. As with any post-market study, there are issues with measurement errors, missing data, and confounding by clinical indication. The definition of failure in this study was designed to be similar to the one used by Dr. Gedde and co-authors in the Tube versus Trabeculectomy Study,[1,2] i.e. failure was defined as IOP greater than 21 mmHg and not reduced by 20% below baseline on 2 consecutive visits after 2 weeks follow-up or repeat surgery. This definition of failure is concerning because it guarantees that those patients who are enrolled with an IOP of 21 mmHg or less are less likely to fail because postoperatively they need a higher IOP than pre-operatively to meet both criteria: IOP greater than 21 mmHg and not reduced by 20% below baseline. If the definition of failure used an "or" instead of an "and", patients would only need one of the criteria to fail so that patients with lower IOPs preoperatively would be as likely to fail as those with higher IOPs. In this study the mean preoperative IOP was 20.0 mmHg with a standard deviation of 6.2 mmHg in patients who had a combined Trabectome® and phacoemulsification. This means that a substantial proportion of subjects had IOPs less than 21 mmHg and were less likely to fail. When failure is defined as IOP greater than 21 mmHg and not reduced by 20% below baseline on 2 consecutive visits after 2 weeks follow-up or repeat surgery, there was a 75% success rate at 12 months in all Trabectome® patients versus when IOP greater than 21 mmHg and not reduced by 20% below baseline on 2 consecutive visits after 2 weeks follow-up or repeat surgery IOP greater than 21 mmHg or not reduced by 20% below baseline on 2 consecutive visits after 2 weeks follow-up or repeat surgery, there was 40% success at 12 months. Although one of the goals of study design and analysis may be consistency with prior studies, there is a risk that relying solely on this earlier conception of "success" will induce misunderstandings with the potential for downstream clinical consequences. Expanding the reporting of results by including both the "and" and the "or" definitions or by including reports of success rates stratified by baseline IOP above or below a certain threshold would broaden the perspective of the clinical audience on the performance of the procedure.

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DR. RICHARD L. LINDSTROM: I consult for AMO who makes a glaucoma tube shunt and I have done some consulting for Glaukos and Transend, who are developing anterior chamber stents. One of the things I have learned by participating in these projects is that cataract surgery alone lowers intraocular pressure more than we thought. One of my associates, Tom Samuelson, who is a glaucoma specialist, and Brooks Poley and Richard Schultz, of Savannah, put together a series of about 600 eyes, from our two practices to determine the impact of cataract surgery alone on intraocular pressure. In the group with mean preoperative IOPs of 22 to 30 mm Hg, phacoemulsification with a posterior chamber lens alone lowered the IOP about 7mm Hg. I think one of the things we need to have, as well as the control group of just Trabectome ® or Trabectome® plus phacoemulsification, is perhaps phacoemulsification alone group. I believe that phacoemulsification without a glaucoma implant lowers pressure as much as the glaucoma drainage device does. This is going to require us, as we go forward, to set a higher standard for glaucoma operations. It may turn out that one of the most effective glaucoma operations available is to simply take out the cataract and place a posterior chamber IOL.

DR, ALBERT W. BIGLAN: No financial conflict, or other conflicts of interest.This is a very exciting instrument. Back in the late 40's and early 1950's Otto Barkan used a knife to treat glaucoma. It was initially used in chronic open-angle glaucoma or primary open-angle glaucoma but was later applied to the eyes of children. When you report your data, I would encourage you to consider breaking out a group or cohort of children 2 years of age and younger, and to report those results separate from your adults. Also, consider using a lower pressure criteria as a consideration for success, perhaps 18 to 20mm. This is a very exciting instrument and I think it will prove to be of value to those of us who treat pediatric glaucoma. Thank you for your presentation.

No financial conflict or other conflicts of interest.

DR. EDWARD L. RAAB. No conflict. I share Dr. Biglan's enthusiasm about the possible use of this instrument in children. I want to ask you about the 8-month old baby. I assume that the surgical intervention was for the treatment of a developmental glaucoma. If my assumption is correct and, unless my understanding is outdated, the possible mechanisms of developmental glaucoma in infants do not include abnormalities in Schlemm's canal. With the use of this instrument do you find it necessary to get into Schlemm's canal and actually perform some ablation? Should I infer that you think this is the mechanism that explains intraocular pressure elevation in congenital glaucoma? If you believe that it is, how would the application of the Trabectome® explain the success of goniotomy that does not involve ablation of Schlemm's canal?

DR. DON MINCKLER. Perhaps I can work backwards. Dr. Raab's comments are well taken. I might point out there is an extensive literature from Sweden, of which I only recently became aware, that suggests most adult or many cases of adult glaucoma are congenital in origin by virtue of a developmental membrane. This finding presumably would be something similar to what Barkan described as a membrane vaulting over the meshwork in the eyes of children with congenital glaucoma. I mention this because a few times we have observed a membrane-like structure peeling off the trabecular meshwork during this procedure. The tissue that we have been able to recover, as I have shown briefly, is either trabecular meshwork or fragments of the meshwork and Descemet's membrane. It does not seem to be a distinct membrane. My concept of pathogenesis in this case is that the abnormal covering of the trabecular meshwork by iris may have impaired aqueous humor outflow. The procedure does not obliterate Schlemm's canal, as far as we know, but rather removes a strip of trabecular meshwork and inner wall of Schlemm's canal. Incidentally, I had performed trabeculectomies after failed trabeculotomies on this child's father when he was about five, and remarkably the father is still seeing. The reason we determined this child had congenital glaucoma was supported by the fact that under careful observation his globe enlarged. His corneas were clear, but the corneal diameter expanded, and he developed increased disc cupping with documented intraocular pressures in the mid 20s. Trabeculotomy and goniotomy, in my view, are actually variations of the same procedure, in the sense that you are cutting through the trabecular meshwork into Schlemm's canal. After reviewing Barkan's original drawings, it is quite clear to me that that his concept included penetrating into Schlemm's canal. How could one otherwise explain the back-bleeding or bleeding into the anterior chamber after goniotomy in children that is rather a common intraoperative problem? With traditional ab externo trabeculotomy, we are obviously rupturing through the inner wall of Schlemm's canal. Among the other theoretical advantages of Trabectome® in children and adults is the removal of inflammatory debris by aspiration during the procedure and not leaving charred tissue in the angle.

Dr. Biglan, perhaps these comments have answered some of the questions you had posed. I agree that we should breakout the data on children as soon as we have sufficient numbers. Currently we only have about 20 cases that, by some stretch of the imagination, could fit into this category, and we have not analyzed them separately. At present I see relatively few babies with congenital glaucoma.

Dr. Lindstrom brings up an excellent point regarding cataract extraction that alone lowers intraocular pressure. The literature with which I am familiar on this subject suggests an IOP reduction of about 2 mmHg, rather than the 7 mm you quoted. Everyone's own expectations depend on whose results you accept. In our experience with combined Trabectome® and cataract surgery, we observed about 5 mm Hg lowering. We believe that there is a significant difference, at least based on our own data. We plan a randomized prospective trial to compare phacoemulsification alone with combined Trabectome® and phacoemulsification. I think such a study will be relatively easy to complete in a multicenter manner, and we are in the process of organizing it now.

I want to thank Anne for her comments, and indeed we have gone back and forth about how to define "success" and "failure" in this study. As all of you know, adjustments in the definitions of success can make a huge difference in statistical outcomes. The solution Anne suggests, providing survival curves based on both "and" and "or" criteria, makes perfect sense and would provide the reader with a more complete picture of the range of outcomes. Thank you all, I have very much appreciated the discussion.